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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,478

07/11/2007

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EXAMINER

LOUIS, LATOYA M

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,478	<b>Applicant(s)</b> CROWDER ET AL.	
	<b>Examiner</b> LaToya Louis	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26,32 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26,32 and 62-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. This office action is responsive to the preliminary amendment filed 4/21/2010. As directed by the amendment, claims 27-31 and 33-61 have been cancelled, and no claims have been added or amended. Thus claims 1-26, 32, and 62-65 are currently pending.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10-12 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, the limitation “the signal trace” lacks antecedent basis.

Regarding claim 17, the limitation of the ceiling lacks antecedent basis.

Claims 11 and 12 are rejected for their dependency on a rejected claim.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 32, and 62-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Ede et al. (7,588,030).

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Regarding claim 1, Ede teaches from figs. 1a through 2, a multi-dose blister package having a plurality of blisters (20) thereon and adapted for use in an inhaler, comprising: a frame (10) member having opposing top and bottom surfaces with a plurality of spaced apart gap spaces (18), a respective gap space configured to define at least a portion of a sidewall (16) of a respective blister; and a floor (14) comprising a flexible material attached to the bottom surface of the frame member so that the floor extends under each gap space to define a bottom of each blister.

Regarding claim 32, Ede teaches a method for fabricating a multi-dose blister package having a plurality of blisters thereon and adapted for use in an inhaler, comprising: providing a generally rigid frame member (10) (i.e. col. 6 lines 22-23 discloses that the frame can be made of metal or ceramics and col. 8 lines 50-51 disclose that the openings in the frames could be formed by drilling) having opposing top and bottom surfaces with a plurality of spaced apart gap spaces (18), a respective gap space configured to define at least a portion of a sidewall (16) of a respective blister; placing a metered quantity of dry powder in each of the blisters (col. 13 lines 27-32); and sealing a floor comprising a flexible material to the bottom surface of the frame member so that the floor extends under each gap space to define a bottom of each blister (col. 13 lines 33-39).

Regarding claim 62, Ede teaches in figs. 1-3 a multi-dose dry powder package comprising: a polymeric frame body (10) (col. 6 lines 22-23) comprising a plurality of spaced apart drug apertures (18); a metered quantity of dry powder medicament (26) held in each of the drug apertures; and a detachable floor (i.e. sheets 12 or 14 as detachable floor) attached to the frame body apertures.

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Regarding claim 63, Ede teaches from fig. 9 that the polymeric frame body has an upper primary surface (i.e. 62) that defines a generally rigid ceiling over the plurality of spaced apart drug apertures (col. 7 lines 47-50 discloses an anvil plate 62 as upper surface which is generally rigid. Alternatively, the top surface of frame 10 defines the shape of the ceiling and the frame body is disclosed as rigid in col. 6 lines 22-38).

Regarding claim 64, Ede teaches that the spaced apart apertures (18) are through apertures (col. 5 line 61), the package further comprising a sealant layer (i.e. sheets 12 or 14) disposed over the frame body to define a ceiling over each of the apertures.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 1-11, 13-15, 17-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey et al. (WO 01/68169) of record in view of Ede.

Regarding claim 1, Hickey teaches from figs. 1 and 3A a multi-dose blister package having a plurality of blisters (40) thereon and adapted for use in an inhaler, comprising: a floor (the combination of barrier 35, pads 25u,25b and substrate layer 28 as floor. Alternatively, sealant layer 45 as floor, depending on the orientation of the device) comprising a flexible material (page 19 lines 29-31) and the floor extends under each blister (40) to define a bottom of each blister but does not teach a frame member having opposing top and bottom surfaces with a plurality of spaced apart gap spaces, a respective gap space configured to define at least a portion of a sidewall of a respective blister. However, Ede teaches a frame member (10) having opposing top and bottom surfaces with a plurality of spaced apart gap spaces (18), a respective gap space configured to define at least a portion of a sidewall (16) of a respective blister (20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the blister pack of Hickey with the frame member as taught by Ede to allow for larger numbers of doses to be contained as taught by Ede in col. 3 lines 36-40.

Regarding claim 2, the modified Hickey teaches from fig. 5 of Ede that the frame gap spaces (18) are through apertures and a ceiling (i.e. 12) attached to the top surface of the frame member so that the ceiling extends above each gap space to define a top of each blister.

Regarding claim 3, Hickey teaches that the ceiling comprises a flexible material (page 21 line 25 discloses that the ceiling can be torn open) having sufficient structural rigidity to be able to define a plurality of spaced apart projections therein (i.e. sealing ridges 129;fig. 7 or metal

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transmission line 26u as spaced apart projections), configured to be in proper relationship with the frame member through apertures so that a respective projection is above a corresponding frame member aperture and the ceiling defines the top of a respective sealed blister and the ridges 129 define the ceiling.

Regarding claim 4, Hickey teaches a bolus quantity of dry powder (30) disposed in respective blisters and the modified Hickey teaches that the frame member is substantially rigid (col. 6 lines 22-35 of Ede).

Regarding claim 5, Hickey teaches that the floor comprises first and second flexible layers of different materials (i.e. barrier 35 and substrate 28) the substrate 28 comprising a flexible piezoelectric material (page 16 line 21), and wherein, in operation, the piezoelectric material underlying a target blister is configured to repeatedly flex generally upward and downward upon receipt of an electrical input (page 18 lines 3-8).

Regarding claim 6, Hickey teaches that the floor second layer comprises the piezoelectric material (a piezoelectric polymer is disclosed on page 14 line 25) and is attached to a bottom of the floor first layer (i.e. 35), the floor second layer further comprising a predetermined conductive pattern (i.e. trace pattern 22u or 22b) disposed over a first primary surface (upper surface u or bottom surface b) and a conductive material (i.e. metal) disposed over at least a portion of an opposing second primary surface (upper surface 21u or bottom surface 21b).

Regarding claim 7, Hickey discloses that the conductive material on the second primary surface (i.e. 21u) of the second layer comprises a metalized coating disposed to cover substantially all of the second primary surface (page 20 lines 1-17).

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Regarding claim 8, Hickey teaches in fig. 3 that the predetermined conductive pattern on the second layer comprises a plurality of spaced apart conductive regions (i.e. the region surrounding pad 25u as conductive region), each region sized and configured to substantially cover a surface area of a bottom portion of a respective blister underlying each gap space.

Regarding claim 9, Hickey teaches that the predetermined conductive pattern further comprises at least one signal trace (26u) extending away from each region.

Regarding claim 10, Hickey teaches that the signal trace (26u) for each blister travels toward a contact zone (i.e. contact pad 25u) on the first primary surface (21u) of the second layer (28) to allow selective electrical excitation of at least one target blister in operation.

Regarding claim 11, Hickey teaches from figs. 2 and 4 that the ceiling (45) and first layer (i.e. 35) of the floor have a circular shape when viewed from the top with respective substantially aligned center apertures (20o) that define a window to expose a portion of an upper surface of the second layer (page 17 lines 16-31 disclose that the opening defines a window for access to the electrical connections of the upper surface of the second layer).

Regarding claim 13, Hickey teaches from fig. 5C that neighboring pairs of blisters comprise a different dry powder held therein (page 22 lines 6-7).

Regarding claim 14, Hickey teaches from fig. 5C that neighboring pairs of blisters are positioned closer to each other than non-neighboring blisters, and wherein each blister of a pair of neighboring blisters includes a different dry powder held therein (page 22 lines 6-7).

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Regarding claim 15, Hickey discloses that the neighboring blisters are sized and configured to, in operation and in position in an inhaler, release their dry powders substantially concurrently to a user upon inhalation (page 22 lines 1-3).

Regarding claim 16, the modified Hickey teaches from figs. 2 and 3 of Ede that the frame member (10) has a thickness that is greater than the thickness of the floor (i.e. 14) and ceiling (i.e. 12) combined.

Regarding claim 17, the modified Hickey discloses that the frame member is a laminated structure (col. 6 lines 24 and 31 of Ede disclose that the carrier 10 as frame can be made of composites as laminated) having increased structural rigidity relative to the floor and/or ceiling (col. 7 line 43 of Ede discloses that the sheets i.e. 12 can be made from foil while col. 6 lines 21-30 of Ede disclose that the frame can be made of metal or ceramic and can have holes punched through it).

Regarding claim 18, the modified Hickey discloses that the frame member is a unitary polymer structure having increased structural rigidity relative to the floor (col. 6 lines 22-23 of Ede discloses that the frame can be a polymer and col. 7 line 43 of Ede discloses that the sheets i.e. 12 can be made from foil).

Regarding claim 19, the modified Hickey teaches from fig. 3 of Ede that the frame member has a primary upper surface (12) that defines a ceiling above the gap spaces.

Regarding claim 20, Hickey teaches in fig. 3A and 10A a generally planar sealant layer (i.e. barrier 35 or substrate 28) disposed over the blister to define a ceiling when the device is an upside-down orientation.

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Regarding claim 21, Hickey teaches that the ceiling (28) comprises a piezoelectric polymer (page 19 lines 22-23).

Regarding claim 22, Hickey teaches that the ceiling (45) is a sealant polymer coating (page 6 line 22) and can thus be deduced to be moisture resistant. In addition page 15 lines 25-26 disclose moisture resistant barriers. However, Hickey does not specifically disclose that the ceiling comprises foil. Ede however teaches a ceiling with moisture resistant foil (col. 4 lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the ceiling with polymer coating of Hickey with the moisture resistant foil as taught by Ede to provide increased sealing ability with the device and increased moisture resistance. It is noted that aluminum foil with polymer coatings are old and well known in the art.

Regarding claim 23, Hickey discloses that the second layer of the floor comprises a piezoelectric polymer (page 14 lines 25-26).

Regarding claim 24, the modified Hickey discloses that opposing sidewalls of a respective gap space are inclined so that the sidewalls taper farther away from each other from a bottom to top portion thereof (col. 10 lines 28-37 of Ede disclose that the walls can be angled 3 degrees from 90 with a wider opening at the top).

Regarding claim 26, Hickey teaches a power source (150); an input signal generating circuit (125) that is in communication with the power source and is configured to provide electrical input to selectively flex the floor of a target blister (page 25 lines 22-32); and computer readable program code (page 26 lines 9-12) that is in communication with the signal

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generating circuit and is configured to define at least one predetermined non-linear vibration input signal selected to represent *a priori* flow characteristic frequencies of the dry powder held in the blisters (page 26 lines 1-12).

9. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ede in view of Hickey.

Regarding claim 65, Ede teaches from fig. 1d a circumferential row of spaced apertures for medicament but does not specifically teach that the spaced apart apertures comprise two generally concentric rows of circumferentially spaced apart apertures. However, Hickey teaches from figs. 6A and 6B two rows of drug containment wells. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Ede with two rows of wells as taught by Hickey to provide for two different ingredients separated before use to be jointly administered as taught by Hickey in page 22 lines 5-7.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey in view of Ede, as applied to claim 1 and 10 above, and further in view of Newell et al. (4,627,432).

Regarding claim 12, Hickey teaches in fig. 1 and page 18 lines 9-16 rotating the blister package but does not specifically disclose a rotatable gear having circumferentially spaced apart gear teeth, the gear being proximate the window of the aligned center apertures and attached to the frame member so that the blister package rotates with the gear. However, Newell teaches in fig. 1 a rotatable gear (12) having circumferentially spaced apart gear teeth (the grooved notches

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around the gear as teeth), the gear being located in the center so as to be able to be proximate the window of the aligned center apertures and attached to the frame member (10) so that the blister package (8) rotates with the gear. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the rotary means of Hickey with the centered gear as taught by Newell to provide a rotary means that won't interfere with the electrical traces and couplings.

11. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey in view of Ede, as applied to claim 1 above, and further in view of Casper (2007/0181124).

Regarding claim 25, the modified Hickey discloses that the walls can be inclined with rounded end (col. 9 lines 56-58 of Ede) but does not specifically disclose that the walls can be coned shaped having substantially constant angles of inclination of between about 20-40 degrees from a bottom to a top portion thereof. However, Casper teaches in figs. 5b and 6b side walls of a blister that are coned shaped with an angle of inclination of approximately 40-45 degrees. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the sidewalls of the modified Hickey with the cone shaped angle of inclination as taught by Casper as such would be considered a design choice, requires a mere change in shape of a component, and would function equally well.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Gumaste (2002/0078947) discloses a crowned shape blister package with piezoelectric element.

Allan (6,871,647) discloses an inhaler with frame and ceiling.

Snow (2002/0134383) discloses a blister package with frame, ceiling, and floor.

Schuler (2001/0035184) discloses a blister pack with ceiling protrusions.

Ohki et al. (6,810,872) discloses a blister pack with protrusions.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya Louis whose telephone number is (571) 270-5337. The examiner can normally be reached on Monday-Friday, 8:30am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LaToya Louis/  
Examiner, Art Unit 3771  
9/24/2010

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772